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6. AUTHOR(S)
Ravishankar Jayadevappa, Ph.D.

20040602 028

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
The University of Pennsylvania
Philadelphia, Pennsylvania 19104-6205

E-Mail: jravi@mail.med.upenn.edu

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13. ABSTRACT (Maximum 200 Words)

The objective of this study is to assess the effects of differential treatments for PC on quality of life and cost of care for the elderly across ethnic groups. Another issue of interest is the comparison of cost and quality of care for PC provided in two distinct health care systems: Veterans Affairs (VA) and non-VA. Three specific study aims are: (1) to analyze and compare the quality of life and satisfaction with care of PC patients across two ethnic (African Americans and Caucasians) groups, controlling for stage at diagnosis and co-morbidity; (2) to analyze and compare the average cost of care of PC patients across two ethnic groups, controlling for the stage at diagnosis and co-morbidity; and (3) to analyze and compare resource utilization, treatment modalities, and cost of PC care between VA and non-VA hospital. During the first two years of this prospective cohort study, we recruited 316 patients form the Urology and Radiation Oncology clinics, University of Pennsylvania Health System and VA medical center. Of these, 209 have completed 3-month follow-up survey and 151 have completed the 12 month follow-up surveys. The preliminary results have helped the PI in securing a Prostate Cancer scholar award from the DOD and a R03 grant from the NIH.

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TITLE: Quality of Life and Cost of Care of Prostate Cancer
        Patients

PRINCIPAL INVESTIGATOR: Ravishankar Jayadevappa, Ph.D.

CONTRACTING ORGANIZATION: The University of Pennsylvania
                           Philadelphia, Pennsylvania 19104-6205

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
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Table of Contents

INTRODUCTION

Proposed Abstract:

Due to uncertainty in the screening and treatment for prostate cancer, debate on outcomes such as quality of and cost of care continues. Research has shown that the type of treatment received for a given stage of prostate cancer varies by ethnicity and age. Hence, the objective of this study is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for the elderly across ethnic groups. Three specific aims are: (1) to analyze and compare the quality of life and satisfaction with care of prostate cancer patients across two ethnic groups, controlling for stage at diagnosis and co-morbidity; (2) to analyze and compare the average costs of care of prostate cancer patients across two ethnic groups, controlling for stage at diagnosis and co-morbidity; and (3) to analyze and compare resource utilization, treatment modalities and cost of prostate cancer care between VA and non-VA hospitals. This study uses prospective cohort design to assess and compare, across Caucasians and African Americans, the health related quality of life (HRQOL) and cost of care for prostate cancer patients older than 65 years. A total of 280 subjects will be recruited from the Urology and Radiation Oncology clinics at the University of Pennsylvania Health System (UPHS), and the Philadelphia VA Medical Center. Baseline data will be collected within 1-2 weeks after recruitment, with subsequent follow up data collection done at three months interval for two years. We will compare average cost of treatment and quality of life across two ethnic groups, controlling for stage of cancer and co-morbidity. Finally, Markov decision model will be used to analyze and compare cost-effectiveness of prostate cancer treatments across two ethnic groups and comparison will be made between VA and non-VA hospitals.

BODY

The process of recruiting newly diagnosed prostate cancer patients was initiated in February of 2002 and was well established in the year 2003. The specific steps of this process are: (1) contacting the patients; (2) explaining the study; and (3) obtaining the consent.

Task 1. Recruitment of Patients (continued)

    a. Potential patients were contacted at the urology and radiation oncology clinics after introduction by their urologist and radiation oncologist. Newly diagnosed patients were also contacted at their pre-prostatectomy classes, organized by the urology clinic. The newly diagnosed prostate cancer patients were contacted at the Veteran Affairs Medical Center during their urology clinic visit.

    b. Research assistant held a detailed discussion with the patients regarding the study.

    c. Consent was obtained from interested patients

    d. Recruitment of patients

    e. A unique patient identifier was assigned to each patient. This information is maintained as highly confidential at all times.

Table 1 shows the total recruitment for the period between 12/19/2002 to 12/18/2003. Some newly diagnosed prostate cancer patients were at the urology clinics for a second opinion only, and were not eligible for our study. So far, we have obtained baseline data on a total of 316 newly diagnosed prostate cancer patients from the University of Pennsylvania Hospital (n=

239) and from the Philadelphia VA Medical Center (n=77).

Table 1: Recruitment of Newly Diagnosed Prostate Cancer Patients

	Hospital of the University of Pennsylvania			Philadelphia VA Medical Center		
	# of eligible patients	# recruited		# of eligible patients	# recruited	
		<65	≥ 65		<65	≥ 65
TOTAL	443	108	170	128	37	56

Task 2: Preparation of Medical Record Abstractions, Months 1-6:
This task was completed during the first year of the study and was reported in the previous progress report.

Task 3: Base line Data Collection (continued)

For the second year of the study (period between 12/19/2002 to 12/18/2003), we continued to recruit newly diagnosed prostate cancer patients from the urology and radiation oncology clinics at the University of Pennsylvania Health System (UPHS). We have also continued to recruit patients from the Philadelphia VA Medical Center. After obtaining a written consent from the patient, we collect patient's baseline demographics and quality of life data using the UCLA prostate cancer index and SF-36. The subsequent follow-ups are done at three months interval for a period of two years beyond a patient's entry into the study. Data on following variables is obtained: Age, ethnicity, types of insurance, living arrangement, marital status and mortality. All the baseline data has been entered and data cleaning is ongoing.

Task 4: Administration of Patient Satisfaction Questionnaire (Continued)
The patient satisfaction care (CSQ8) survey was administered at baseline and at each subsequent follow-up. All patient data satisfaction data has been entered and data cleaning is ongoing.

Patient Follow-up and Retention

Task 5: Develop Plan for Follow-up Patient interview (continued)
a. A tracking system was developed to track the patient recruitment and contact process. During the follow-up period, five patients died, three from the UPHS and two from the VA. Table 2 shows patient retention and follow-up. We provide each patient with $10 in compensation at the time of recruitment into the study and $5 at each successful follow-up. This has helped in generating good response rates.

Table 2: Patient follow-up and retention

	HUP		VA	
	# patients recruited	# of surveys completed	# patients recruited	# of surveys completed
Baseline	278	239	93	77
	# eligible for follow-up	# of surveys completed	# eligible for follow-up	# of surveys completed
3 month	176	163	60	46
6 month	156	145	60	57
12 months	130	125	30	26

Task 6: Follow up interview and Health Related Quality of Life, and Cost (resource Utilization) Data Collection

a. Surveys were sent out at every three months to collect data from enrolled patients.

b. Non-respondents were contacted over the telephone and were offered the option to complete the survey over the telephone.

c. Data collection and data entry is being done simultaneously.

d. Date of diagnosis, date of treatment & length of stay, other relevant medical diagnoses and medications data are being obtained from medical charts.

e. Health Related Quality of Life data is collected using SF-36 and UCLA Prostate Cancer Index.

For the patients who have completed 18 months into study, we are in the process of obtaining following clinical data via medical chart review: date of diagnosis, date of treatment & length of stay; type of treatment/procedures; hospital charges & reimbursements, number and type of medications; number of other procedures, principal DRG diagnostic studies and relevant medications. Health resource utilization and cost data is being obtained from the Pennsylvania Integrated Clinical and Research (PICARD) database. The PICARD database (www.uphs.upenn.edu/hsr/dbase.shtml) was established to facilitate clinical research in the ambulatory care practices of the UPHS and tracks detailed clinical outcomes by consolidating patient information from multiple sources

Table 3: Demographics of the study group (n= 316)

Variable		Percent
Race	Caucasian	72.20%
	African American	27.80%
Education	8 grades or less	2.16%
	Some high school	7.19%
	High school graduate	24.46%
	Some college	21.58%
	College graduate	14.03%
	Advanced or graduate training	30.58%
Marital status	Married	76.17%
	Single	8.66%
	Widowed	3.97%
	Divorced	11.19%
Current employment status	Working full-time	44.40%
	Working part-time	6.50%
	Retired	41.88%
	Other	7.22%
Household income	Under $10,000	6.24%
	$10,001 up to $20,000	11.19%
	$20,001 up to $30,000	9.70%
	$30,001 up to $40,000	8.96%
	$40,001 up to $50,000	7.09%
	$50,001 up to $70,000	13.43%
	$75,001 or more	43.28%

The demographic characteristics of the study group are presented in table 3. The mean age was 63.19 (sd.= 7.59) years and the mean number of persons in a household was 2.31 (sd.=1.05)

Tables 4 and 5 present the baseline general health and functional status of all newly diagnosed prostate cancer patients (UPHS and VA combined). All raw scores were converted to a scale of 0 to 100. A score of zero indicates extremely limited function/activity, whereas, a score of 100 indicates excellent function/activity. Physical functioning (Table 4) is a measure of activities during a typical day. Lower score on physical functioning is indicative of more limited the movements. Social functioning is a measure of how physical health interferes with social activities with family, friends, neighbors or groups. As mentioned earlier, the score varies from 0 (high problem) to 100 (no problem). Bodily pain indicates presence of bodily pain and its impact on normal work and the score ranges from 0 to 100. A score of 100 indicates no pain and a score of 0 indicates extreme or very sever pain. Vitality measures level of energy, higher score meaning better vitality. Mental health is a measure of emotional well-being. The score on mental health ranges from 0 to 100. Higher score suggests better mental health. Urinary function is a measure of urinary habits. The score varies from 0 to 100. Higher the score, better the urinary function. Bowel function indicates bowel habits and abdominal pain. Higher score on

bowel function indicates better bowel function. Sexual function is a measure of sexual function and sexual satisfaction. The score ranges from 0 to 100, higher score indicating better sexual functions. Similar baseline data for UPHS and VA groups is presented in Tables 6 to 8 and that by ethnicity (African American and Caucasian) is presented in Tables 9 to 11.

Table 4: Overall General Health and Prostate Cancer Index (n= 316) at the baseline

Variable	Mean (standard deviation)
General Health	
Physical functioning	64.62 (21.67)
Role-physical	76.89 (37.87)
Social function	83.36 (22.89)
Bodily pain	82.83 (24.12)
Vitality	66.99 (20.70)
Mental health	76.39 (17.9)
Emotional function	77.74 (36.69)
General health	68.51 (23.35)
UCLA Prostate Cancer Index	
Urinary function	53.05 (11.79)
Bowel function	88.72 (14.37)
Sexual function	54.06 (29.04)
Urinary bother	85.85 (24.71)
Bowel bother	90.72 (17.81)
Sexual bother	63.17 (38.51)

Table 5: Functional Status and Prostate Cancer Index (n=316)

Variable	Percent
General Health	
In general, would you say your health is... Excellent	22.86%
Very good	33.21%
Good	28.57%
Fair	12.50%
Poor	2.86%
Compared to one year ago, how would you rate your health in general now?	
Much better now than one year ago	2.17%
Somewhat better now than one year ago	8.30%
About the same as one year ago	62.09%
Somewhat worse now than one year ago	23.47%
Much worse now than on year ago	3.97%
UCLA Prostate Cancer Index	
Urinary bother : No problem	67.65%
Very small problem	17.65%
Small problem	7.72%
Moderate problem	4.41%
Big problem	2.57%
Bowel bother : No problem	73.53%
Very small problem	18.75%
Small problem	4.78%
Moderate problem	2.94%
Big problem	0.00%
Sexual bother: No problem	43.51%
Very small problem	12.60%
Small problem	12.21%
Moderate problem	16.41%
Big problem	15.27%

Table 6: Comparison of demographics across VA and UPHS groups at the baseline (n=316)

Variable	UPHS (n=239)	VA(n=77)	
Race			
White	88.50%	11.50%	χ= 75.18; df=1
African American	41.38%	58.62%	p= <.0001
Education			
8 grades or less	33.33%	66.67%	χ= 60.17; df=5
Some high school	40.00%	60.00%	p= <.0001
High school graduate	64.71%	35.29%	
Some college	58.33%	41.67%	
College graduate	94.87%	5.13%	
Advanced or graduate training	96.47%	3.53%	
Marital status			
Married	83.89 %	16.11%	χ= 41.31; df=3
Single	41.67%	58.33%	p= <.0001
Widowed	72.73%	27.27%	
Divorced	41.94%	58.06%	
Current employment status			
Working full-time	91.87%	8.13%	χ= 38.41; df=3
Working part-time	77.78%	22.22%	p= <.0001
Retired	60.34%	39.66%	
Other	50.00%	50.00%	
Household income			
Under $10,000	23.53%	76.47%	χ= 145.3; df=6
$10,001 up to $20,000	10.00%	90.00%	p= <.0001
$20,001 up to $30,000	50.00%	50.00%	
$30,001 up to $40,000	66.67%	33.33%	
$40,001 up to $50,000	84.21%	15.79%	
$50,001 up to $70,000	94.44%	5.56%	
$75,001 or more	99.14%	0.86%	

Table 7: Comparison of overall general health and PCI of VA and UPHS groups at baseline

Variable	UPHS (n=239)	VA (n= 77)	p value
Physical functioning	70.45 (15.77)	47.53 (27.07)	<.0001
General Health			
Role-physical	85.81(30.15)	50.00 (45.58)	<.0001
Social function	87.08 (19.79)	72.54 (27.59)	<.0001
Bodily pain	89.19 (17.09)	64.19 (31.21)	<.0001
Vitality	70.61(18.63)	56.25 (22.87)	<.0001
Mental health	78.27 (16.4)	70.92 (20.93)	0.0083
Emotional function	81.07 (34.42)	67.65 (41.52)	<.0001
General health	73.68 (20.91)	53.47 (23.70)	<.0001
UCLA Prostate Cancer Index			
Urinary function	53.84 (11.42)	50.79 (12.59)	0.0593
Bowel function	90.82 (13.17)	82.84 (16.01)	0.0003
Sexual function	57.41 (28.17)	43.90 (29.49)	0.0010
Urinary bother	87.94 (23.33)	79.93 (27.59)	.0187
Bowel bother	92.29 (16.09)	86.27 (21.46)	.0332
Sexual bother	64.16 (38.49)	60.23 (38.72)	.4743

Table 8 Comparison of functional status and PCI of VA and UPHS at the baseline

Variable		UPHS (n=239)	VA (n= 77)	
General Health				
In general, would you say your health is Excellent		92.19%	7.81%	χ= 66.01
	Very Good	90.32%	9.68%	df=4
	Good	63.75%	36.25%	p= <.0001
	Fair	40.00%	60.00%	
	Poor	12.50%	87.50%	
Compared to one year ago, how would you rate your health in general now?				
	Much better now than one year ago	66.67%	33.33%	χ=9.82
	Somewhat better now than one year ago	78.26%	21.74%	df= 4
	About the same as one year ago	80.23%	19.77%	p= .0435
	Somewhat worse now than one year ago	61.54%	38.46%	
	Much worse now than on year ago	63.64%	36.36%	
UCLA Prostate Cancer Index				
Urinary bother	No problem	78.26%	21.74%	χ=8.62
	Very small problem	70.83%	29.17%	df=4
	Small problem	52.38%	47.62%	p= .0714
	Moderate problem	58.33%	41.67%	
	Big problem	71.43%	28.57%	
Bowel bother	No problem	77.00%	23.00%	χ=10.05
	Very small problem	72.55%	27.45%	df=3
	Small problem	38.46%	61.54%	p=.0182
	Moderate problem	62.50%	37.50%	
	Big problem	0.00%	0.00%	
Sexual bother	No problem	78.77%	21.93%	χ= 2.63
	Very small problem	69.70%	30.30%	df= 4
	Small problem	68.75%	31.25%	p= .6216
	Moderate problem	79.07%	20.93%	
	Big problem	70.00%	30.00%	

Table 9: Comparison of demographics across ethnicity at the baseline

Variable	Caucasian (n=226)	African-American (n=87)	
Education			
8 grades or less	33.33%	66.67%	χ= 49.84
Some high school	35.00%	65.00%	df=5
High school graduate	63.24%	36.76%	p= <.0001
Some college	67.80%	32.20%	
College graduate	86.84%	13.16%	
Advanced or graduate training	95.24%	4.76%	
Marital status			
Married	80.86%	19.14%	χ= 24.68
Single	66.67%	33.33%	df=3
Widowed	63.64%	36.36%	p= <.0001
Divorced	40.00%	60.00%	
Current employment status			
Working full-time	86.78%	13.22%	χ= 29.24
Working part-time	77.78%	22.22%	df=3
Retired	66.96%	33.04%	p= <.0001
Other	35.00%	65.00%	
Household income			
Under $10,000	29.41%	70.59%	χ= 97.05
$10,001 up to $20,000	23.33%	76.67%	df=6
$20,001 up to $30,000	53.85%	46.15%	p= <.0001
$30,001 up to $40,000	83.33%	16.67%	
$40,001 up to $50,000	61.11%	38.89%	
$50,001 up to $70,000	85.71%	14.29%	
$75,001 or more	95.65%	4.35%	

Table 10: Comparison of mean scores of general health and PCI across ethnicity at the base line

Variable	Caucasian (n= 226)	African American (n=87)	p value
General Health			
Physical functioning	68.83 (18.12)	52.47 (26.29)	<.0001
Role-physical	83.29 (33.28)	57.25 (44.37)	<.0001
Social function	87.32 (19.29)	73.09 (28.04)	<.0001
Bodily pain	86.85 (21.15)	71.09 (28.33)	<.0001
Vitality	69.57 (20.07)	59.46 (21.22)	.0004
Mental health	78.39 (16.33)	70.70 (21.27)	.0066
Emotional function	81.45 (33.09)	65.22 (44.07)	.0050
General health	72.48 (21.62)	57.43 (24.64)	<.0001
UCLA Prostate Cancer Index			
Urinary function	53.34 (12.07)	52.03 (11.22)	.4237
Bowel function	89.19 (15.38)	87.39 (11.24)	.3032
Sexual function	54.80 (29.26)	52.01 (28.71)	.4938
Urinary bother	86.11 (25.25)	84.51 (23.67)	.6410
Bowel bother	90.40 (18.75)	91.19 (15.29)	.7252
Sexual bother	64.97 (38.38)	58.58 (38.57)	.2422

Table 11: Comparison of functional status and PCI across ethnicity at the baseline

Variable		Caucasian (n=226)	African American (n=77)	
General Health				
In general, would you say your health is				
Excellent		87.50%	12.50%	χ= 42.18
	Very Good	89.01%	10.99%	df=4
	Good	62.50%	37.50%	p= <.0001
	Fair	41.18%	58.82%	
	Poor	62.50%	37.50%	
Compared to one year ago, how would you rate your health in general now?				
	Much better now than one year ago	50.00%	50.00%	χ= 8.69
	Somewhat better now than one year ago	59.09%	40.91%	df=4
	About the same as one year ago	79.41%	20.59%	p= .0694
	Somewhat worse now than one year ago	67.69%	32.31%	
	Much worse now than on year ago	81.82%	18.18%	
UCLA Prostate Cancer Index				
Urinary bother	No problem	75.69%	24.31%	χ= 3.01
	Very small problem	68.75%	31.25%	df=4
	Small problem	61.90%	38.10%	p= .5565
	Moderate problem	75.00%	25.00%	
	Big problem	85.71%	14.29%	
Bowel bother	No problem	74.11	25.89	χ= 4.11
	Very small problem	70.59	29.41	df=3
	Small problem	61.54	38.46	p= .2500
	Moderate problem	100.00	0.00	
	Big problem	0.00	0.00	
Sexual bother	No problem	78.76%	21.24%	χ= 2.75
	Very small problem	69.70%	30.30%	df=4
	Small problem	67.74%	32.26%	p= .6002
	Moderate problem	74.42%	25.58%	
	Big problem	69.23%	30.77%	

Task 7: Indirect Cost Data Abstraction Design

During the first year of the project, a survey to obtain indirect cost data was developed. This survey is sent out with each follow-up to obtain indirect cost data.

Task 8: Abstraction of Medical Records

a. Medical record abstraction is currently being performed and will continue during the follow-up period.

b. Data entry and quality control measures are ongoing.

Task 9: Data entry and coding (continued)

      a. Data dictionary was created

      b. Databases were set up in Microsoft Access and Excel

      c. All the data obtained is being coded and entered (ongoing).

      d. By end of study year two, our database consisted of baseline QOL data on 316 patients, 3 month follow-up data on 209 patients, 6 month follow-up data on 202 patient and 12 months follow-up data on 151 patients.

KEY RESEARCH ACCOMPLISHMENTS

During the second year of the study (between 12/19/2002 to 12/18/2003), we have established the recruitment/follow up mechanism and have continued to recruit patients. We have successfully recruited total of 316 newly diagnosed prostate cancer patients from the Urology clinic, Radiation Oncology clinic of the University of Pennsylvania and VA Medical Center. Patient recruitment as well as data collection on Quality of Life, satisfaction with care, direct and indirect medical cost at baseline and follow-up is ongoing. Upon recruitment, each patient is offered $10 in one time compensation. Additionally, at each follow-up contact, the patient is offered $5 upon completion of surveys. We have found this to be helpful in generating good response rates. Also, another important observation is that involvement of urologist has greatly enhanced the recruitment and retention of patients. During the second year of the study, we have presented the results in four conferences. Preliminary data from this project has helped the PI in acquiring two additional grants on prostate cancer.

REPORTABLE OUTCOMES

I. <u>Peer Reviewed Abstract:</u>

1. Jayadevappa R, Malkowicz B, Chhatre S, Weiner M, Bloom BS. 2003. Cost of Care of Patients with Prostate Cancer Across Age and Ethnicity. The Journal of Urology, 169 (4): 15.

2. Jayadevappa R, Chhatre s, Rosner A, Fomberstein K, Bloom BS, Malkowicz BS. Quality of Life of newly diagnosed Elderly Prostate Cancer Patients. The American Geriatrics Society Annual Conference (under review).

3. Jayadevappa R, Chhatre S, Fomberstein K, Johnson K, Rosner A, Bloom BS, Malkowicz BS, Quality of life of newly diagnosed prostate cancer patients in a public vs. private setting. ISPOR Annual meeting (under review).

4. Jayadevappa R, Chhatre S, Johnson K, Bloom BS, Malkowicz B. Quality of life of newly Diagnosed Prostate Cancer Patients. AcademyHealth-Annual Research Conference (under review).

Manuscripts:

1. Jayadevappa R, Malkowicz B, Weinder M, Chhatre S, Bloom BS. Direct Medical Care Cost of Patients with Prostate Cancer Across Age and Ethnicity. (working paper)

2. Jayadevappa R, Bloom BS, Chhatre S, Malkowicz B. Predictors of Quality of Life Newly Diagnosed Prostate Cancer Patients. (working paper).

Grants:

1.Principal Investigator – Quality of Life in long-term survivors of prostate cancer. NIA-NIH RO3. 4/15/04 – 3/15/06

2.Principal Investigator - Quality of life and Cost Effectiveness of Prostate Cancer Treatment. Department of Defense. 1/1/04 – 12/31/06

3. Principal Investigator - Quality of Life and Cost of Care of Elderly - KO2, AHRQ (under review).

CONCLUSIONS

Most of the proposed targeted activities for year two were achieved in the year. We have a well-established recruitment and retention mechanism in place. The support of Urologist has been very helpful toward this. As of now, we have recruited 316 newly diagnosed prostate cancer patients. We will aim to achieve our goal of recruiting equal number of African Americans in the next few months. The process of data entry and data quality control is well established and ongoing. In addition, we have been able to publish and present the preliminary results. The preliminary data from this study has helped the PI in securing a Prostate Cancer Scholar award and a RO3 from the NIH.

APPENDICES

CONCLUSIONS: General HRQOL in patients undergoing RP as initial treatment can be affected not only by clinical characteristics, but insuarance as well. Future exploration of specific characherisitc of different insurance groups are needed. These findings can have important implication in understanding the provision of necessary services after radical prostatectomy.

Changes from Baseline to Post-Treatment for Significant (P<0.05) Outcomes

	Medicare	Medical+Suppl	Private	FFS	Government
PF	0.89	-4.29	-2.96	-15.3	-13.74
RP	-11.60	-27.61	-9.71	-37.83	-29.76
BP	-3.17	-4.02	-3.65	-14.93	0.12
PCS	-0.75	-3.84	-2.84	-9.60	-5.58

Scored from 0-100; a positive change score indicates improvement.

55

PREDICTORS OF QUALITY OFE LIFE OUTCOMES AFTER RADICAL PROSTATECTOMY: RESULTS FROM CAPSURE™

Jim C Hu*, Los Angeles, CA; Eric P Elkin, David J Pasta, Deborah P Lubeck, San Francisco, CA; Michael W Kattan, New York, NY; Peter R Carroll, San Francisco, CA; Mark S Litwin, Los Angeles, CA

INTRODUCTION AND OBJECTIVE: We investigated the usefulness of patient and tumor characteristics in predicting continence, potency, and physical and mental health 1 year after radical prostatectomy (RP).

METHODS: We studied 372 men drawn from CaPSURE™, a national, longitudinal cohort, who underwent RP alone for prostate cancer. Health-related quality of life (HRQOL) was assessed before and 12 months (range 9-15) after surgery with the Physical and Mental Component Summaries of the RAND SF-36 and the Sexual and Urinary Function scales of the UCLA Prostate Cancer Index. Covariates included clinical T-stage, PSA, Gleason grade, age, race, income, education, comorbidity, and overall health self-rating. Chi-square and backward stepwise multivariate analysis identified differences between men who did and did not return to baseline HRQOL. Return to baseline HRQOL score was set at 90% or greater for physical and mental health, 80% for continence, and 75% for potency.

RESULTS: Of the total, 63%, 20%, 80%, and 86% returned to baseline continence, potency, physical and mental health, respectively. Age <65 years was associated with return to baseline functioning for continence, potency, and physical but not mental health. Univariate analyses also revealed other characteristics to be predictors (p<0.05) of better outcomes: household income > $30,000 (potency, physical health), fewer comorbidities (potency, physical health), excellent or very good health self-rating (mental health). In multivariate analyses, subjects <65 years old were more likely to return to baseline urinary (OR 1.8, p<0.01), sexual (OR 2.5, p<0.01), and physical health (OR 1.8, p=0.03). Furthermore, subjects with no comorbidities were more likely to return to baseline physical health (OR 2.5, p=0.01) while those with an excellent or very good baseline health self-rating were more likely to return to baseline mental health (OR 2.3, p=0.01). Clinical T-stage, PSA, and Gleason grade did not predict return to baseline HRQOL.

CONCLUSIONS: Younger patient age (<65) is associated with a greater likelihood of returning to baseline continence, potency, and physical health after RP. In addition, RP patients without comorbidities and those with high health self-ratings are more likely to return to baseline physical and mental health, respectively. Preoperative tumor characteristics do not appear to be associated with regaining baseline HRQOL, suggesting that factors not measured in this model, such as surgical technique, may be important in optimizing quality of life following RP.

56

COST OF CARE OF PATIENTS WITH PROSTATE CANCER ACROSS AGE AND ETHNICITY

Ravi Jayadevappa*, Stanley B Malkowicz, Mark G Weiner, Sumedha Chhatre, Bernard S Bloom, Philadelphia, PA

INTRODUCTION AND OBJECTIVE: In 1994, the total Medicare expenditure for prostate cancer treatment was $14 billion; however, uncertainty exists regarding the cost effectiveness of treatments. Cost and utility of health status is relevant to health conditions and multiple treatment strategies for prostate cancer provide a unique arena for examining associated costs and utilization of care. The aim of this study is to compare cost and resource utilization of prostate cancer patients across age and ethnic groups.

METHODS: A retrospective cohort study design was used to collect data on 120 African American and Caucasian prostate cancer patients at a large urban academic hospital. The control group consists of 240 (1:2) patients without

prostate cancer, and matched by age. ethnicity and Charlson co-morbidity score. Both cases and control patients were selected from the same health care system database. Through medical chart review and the Pennsylvania Integrated Clinical and Research Database (PICARD) we obtained demographic, clinical and cost data on all patients. Direct costs include costs of care provided by physicians and other health care professionals. Costs are defined as actual charges received for specific services by the respective health care organization (or providers) and we used an average cost to charge ratio of 0.80. Log linear regression model was used to analyze the factors associated with total cost.

RESULTS: The log regression model for the total sample (cases and controls) indicated that the patients with prostate cancer have 57% higher total direct medical cost, whereas age and ethnicity has no direct effect. Also, as expected, Charlson co-morbidity score is positively associated with cost. The log regression model for the prostate cancer patients only shows that ethnicity and Charlson's scores are significantly associated with total cost but age is not.

CONCLUSIONS: Charlson co-morbidity, age, and ethnicity are important factors that associated with the cost of care and type of treatment received by patients with prostate cancer. The effect of co-morbidity on the variations in cost and type of treatment received will require further study.

Variables	African-American (n=60)		Caucasians (n=60)	
	<65 years	>65 years	<65 years	>65 years
Radiation	2(17%)	31(67%)	5(24%)	19(53%)
Surgery	9(75%)	23(51%)	4(19%)	21(58%)
Hormone Therapy	4(31%)	23(51%)	4(19%)	17(47%)
Mean total charges of patients with prostate cancer	$19,628	$19,710	$18,038	$22,511
Mean Prostate cancer charges	$5,731	$4,833	$7,907	$6,727
Mean Incremental charges	$1,131	$1,123	$11,529	$5,165

57

THE ECONOMIC BURDEN OF METASTATIC PROSTATE CANCER PROGRESSION: FINDINGS FROM A RETRO-SPECTIVE ANALYSIS OF HEALTH PLAN DATA

David F Penson*, Seattle, WA; Judd W Moul, Rockville, MD; Christopher P Evans, Sacramento, CA; John J Doyle, New York, NY; Sanjay Gandhi, Wilmington, DE; Lois Lamerato, Detroit, MI; Lisa R Siegartel, Lee S Stern, New York, NY

INTRODUCTION AND OBJECTIVE: To evaluate the economic burden of metastatic progression in prostate cancer (CaP) patients using a cancer registry linked to an administrative database.

METHODS: A retrospective cohort evaluation of 2,056 CaP patients was conducted at a large Midwestern health care system from 1995 to 2000. The database covers 3.5 million lives and contains patient demographics, cancer characteristics, laboratory values, health care encounters (inpatient and outpatient visits, emergency department) and charges for health care services. The patient population was stratified by initial CaP treatment modality. Patient records were examined for any ICD-9-CM codes for determination of metastatic progression. Charges for health care resources charged were identified. Charges six months before and six months after progression were compared using pairwise t-tests. A Generalized Linear Model (GLM) determined the effect of progression on charges while controlling for stage, grade, treatment, and follow-up time. The GLM approach compared the progressed and non-progressed groups based on charges incurred during initial care, continuing care, and terminal care after controlling for age and baseline stage.

RESULTS: CaP patients had a mean age of 68 years, were mostly white (52%), had localized (88%) and moderately differentiated (66%) tumors, and a median baseline PSA of 4.9 ng/ml. 8.9% of patients had metastatic progression within 3.6 years. Median duration of follow-up for progressed and non-progressed patients was 3.7 and 3.4 years, respectively. Progressed patients incurred significantly higher charges compared to non-progressed patients ($30,626 vs. $16,676, p<0.0001), per year. Mean care charges for patients 6 months after metastatic progression ($30,171, N=66) were significantly greater than charges 6 months preceding progression ($20,690, p=0.006). Metastatic progression resulted in a significant increase in charges (p<0.0001) while controlling for baseline covariates. Tukey post hoc comparisons indicated that progressed patients incurred significantly more charges in initial (p=0.012) and continuing care (p<0.001) as compared to non-progressed patients.

CONCLUSIONS: In CaP patients, metastatic progression poses a significant economic burden, irrespective of baseline stage, grade, and treatment. Effective treatments that avoid or delay progression to metastasis could offset the cost of progression.

QUALITY OF LIFE OF NEWLY DIAGNOSED PROSTATE CANCER PATIENTS IN A PUBLIC VS. PRIVATE SETTING

Authors: Ravishankar Jayadevappa, PhD; Sumedha Chhatre,PhD; Kenneth Fomberstein; Katarina Johnson; Andrew Rosner; Bernard S. Bloom, PhD; Bruce Malkowicz, MD

Corresponding Author:
Ravishankar Jayadevappa, PhD
Research Assistant Professor
Department of Medicine
University of Pennsylvania
224, Ralston-Penn Center
3615 Chestnut Street
Philadelphia PA 19104-2676
Email: jravi@mail.med.upenn.edu
Tel: 215-898-3798
Fax. 215-573-8684

(a) Objective: Demographic, clinical, social and economic factors influence the Health Related Quality of Life (HRQOL) and must be assessed in the management and treatment of diverse prostate cancer (PC) patients. Our study objective is to analyze the variations in QoL of newly diagnosed PC patients over the course of three months between public and private facilities.

(b) Methods: 316 newly diagnosed PC patients recruited from the urology clinics of a private urban academic hospital and a veterans hospital completed SF-36 and UCLA-PCI prior to treatment, and at 3-month follow-up.

(c) Statistical Analysis and Results: General and Prostate-Specific QoL and demographics were compared across public and private facilities using t-test and chi-sq. Demographic characteristics varied significantly between the two groups. Privately-treated patients were predominantly Caucasian (83.68%), whereas publicly-treated patients were predominantly African American (66.23%, p < .0001). Privately-treated patients had significantly higher income and education levels, were significantly more likely employed and married (61.35% vs. 20.00%; 54.59% vs. 14.29%). Baseline mean scores of general QoL demonstrated that publicly-treated patients were substantially less healthy by physical, psychological and social measures (mean physical function score of 47.53 compared to 70.46 for privately-treated patients (p < .0001)). This was true for the PC-specific HRQoL also, though the differences were smaller. After three months, the mean scores for both groups declined from baseline levels though the groups' relative divergence narrowed. Publicly-treated patients remained substantially less healthy as indicated by general HRQoL scores. However, for PC-specific QoL, their means scores on sexual and urinary function, and sexual and urinary bother were significantly higher than privately-treated patients.

(d) Conclusions: Baseline and 3-month HRQoL of newly diagnosed PC-patients vary across different treatment settings. Further analysis into the baseline determinants of QoL and their effect on subsequent changes in QoL are crucial for effective management of prostate-cancer.

Title: Quality of Life of newly diagnosed Elderly Prostate Cancer Patients

Authors: Ravishankar Jayadevappa, PhD; Sumedha Chhatre,PhD; Andrew Rosner; Kenneth Fomberstein; Bernard S. Bloom, PhD; Bruce Malkowicz, MD

(a) Introduction: Multiple factors (demographics, clinical, social and economic) influence the Health Related Quality of Life (HRQoL) and need to be assessed in the management and treatment of elderly prostate cancer patients. **Objective:** to compare HRQoL of newly diagnosed elderly prostate cancer patients from VA and non-VA hospitals at baseline and at 3 month follow-up. **Methods:** From our prospective study database, we used a subset of 115 elderly ($\geq$ 65 yrs) prostate cancer patients recruited from the urology clinics of an urban academic hospital and the VA hospital at the time of diagnosis. Patients completed SF-36 and UCLA-PCI prior to their treatment and at 3 month follow-up. Demographics were compared across VA and non-VA groups using t-test and chi-sq. Similarly, the HRQoL comparison was done at baseline and at 3 month follow-up. Log linear regression models were used to assess factors associated with generic and prostate cancer specific HRQoL. Independent variables were age, ethnicity, income, marital status and type of hospital. **Results:** Non-VA group had significantly higher income, education and better general health. As shown in Table 1, some subscale scores of generic HRQoL were significantly higher for non-VA group at baseline. Prostate cancer specific HRQoL scores at baseline for urinary and bowl function were higher for non-VA group. At 3 month follow up, the non-VA group continued to have higher scores on physical and urinary function. Regression results indicated that at baseline, higher education was positively associated with many generic HRQoL subscales. For prostate cancer specific HRQoL, age, income and non-VA status were positively associated with bowel function and urinary bother. **Conclusions:** Variations exist in the characteristics and HRQoL of newly diagnosed prostate cancer patients across VA and non-VA hospitals. Income, age, education and non-VA hospital status appeared to influence the generic and prostate cancer specific HRQoL. Further analysis of the factors associated with long term HRQoL from diverse hospitals settings is critical for effective management of prostate cancer.

Table 1: Baseline HRQoL for Elderly Patients (n=115)

Sub scales	HUP group (n=81) Mean±SEM	VA group (n=34) Mean±SEM	p value
Generic HRQoL			
Physical function	58.2±11.0	39.9±21.9	<.0001
General health	42.3±16.0	20.9±22.6	<.0001
Social function	43.8±15.0	32.4±20.5	.005
Bodily pain	47.4 ±6.5	49.4 ±10.5	.317
Mental health	52.8±8.8	53.9±9.5	.559
Role physical	40.1 ±4.6	37.1±9.7	.086
Vitality	28.7±11.8	25.9±21.2	.093
Role emotional	37.8±7.9	47.3±10.5	<.0001
Prostate cancer specific HRQoL			
Urinary function	53.5±11.6	49.3 ±12.2	.081
Bowl function	91.8±9.1	82.5±18.3	.008
Sexual function	45.3±28.3	32.3±27.3	.034
Urinary bother	87.9±20.1	79.5±28.9	.134
Bowl bother	92.5±13.5	85.6±21.7	.096
Sexual bother	56.1±40.3	65.0±38.6	.303
Mean age	68.4±4.2	70.8 ± 5.2	.014

Title: Quality of life of newly Diagnosed Prostate Cancer Patients

Authors: Ravishankar Jayadevappa, PhD; Sumedha Chhatre,PhD;
Katarina Johnson; Bernard S. Bloom, PhD; Bruce Malkowicz, MD

Corresponding Author:
Ravishankar Jayadevappa, PhD
Research Assistant Professor
Department of Medicine
University of Pennsylvania
224, Ralston-Penn Center
3615 Chestnut Street
Philadelphia   PA 19104-2676

Email: jravi@mail.med.upenn.edu
Tel: 215-898-3798
Fax. 215-573-8684

(a) Introduction and Objective: Quality of life has become an integral part of cancer outcome research. Multiple factors (demographic, clinical, social and economic) influence the Health Related Quality of Life (HRQoL) and must be assessed for effective management and treatment of diverse prostate cancer (PC) patients. Little information is available regarding effects of differential treatment patterns for ethnic or age groups on quality of life of newly diagnosed PC patients. The objective of this study is to analyze the variations in HRQoL of newly diagnosed PC patients by ethnicity and age over a 3-month follow-up.

(b) Methods and Statistical Analysis: For this prospective study, we recruited 316 newly diagnosed PC patients from the urology clinics of an urban academic hospital and Veterans Administration hospital. Participants completed SF-36 and UCLA-PCI surveys prior to their treatment, and at 3-month follow-up. Demographics and HRQoL were compared across ethnicity using t-test and chi-sq. Log linear regression model was used to assess factors associated with general and PC-specific HRQoL. Independent variables were age, ethnicity, treatment facility, income, marital and surgical status.

(c) Results: Caucasians (C) had significantly higher income, education and were more likely employed. For Caucasians there was no significant variation in education by age (some college or greater: <65 C = 75.2%,   65 C = 73.81%), however African Americans (AA) showed significant variation (among <65 AA, 51.11% had some college or greater; in the   65 AA, 80% were high school graduates). Caucasians and AA showed no important variation in marital status by age, however more AA lived alone than Caucasians. Type of treatment varied significantly across ethnicity, more Caucasians received surgery (71.25% C vs. 44.19% AA, p = .0009) whereas more AA received radiation treatment (13.13% C vs. 25.58% AA, p = .047). Baseline mean scores of general HRQoL demonstrated that AA were substantially less healthy by all

physical, psychological and social measures. The PC-specific HRQoL did not differ by ethnicity. At 3-months, general HRQoL scores remained significantly higher for Caucasians except for vitality, mental health, and social function. The mean scores for both groups in general HRQoL and PC QoL declined from baseline levels, though the groups' relative divergence narrowed. PC-specific QoL demonstrated important differences by ethnicity. Caucasians reported significantly greater bowel function (87.86 C vs. 81.47 AA, p = 0.02) and less bowel bother (88.75 C vs. 78.41 AA, p = 0.006), while AA reported significantly greater sexual function (20.74 C vs. 29.06 AA, p = 0.045). Regression analysis for baseline data indicated that income and presence of other illnesses were significantly positively associated with general health and physical function. Regression analysis for the 3-month follow-up data indicated that patients receiving surgery demonstrated significant negative association with urinary function.

(d) Conclusions: Variations exist at baseline characteristics and HRQoL of newly diagnosed PC patients by ethnicity. The 3-month, the variations in HRQoL by ethnicity narrowed as HRQol for both the ethnic groups declined. Assessment of HRQoL and comorbidities is crucial for effective management of PC.